UNITED STATES DEPARTMENT OF COMMERCE
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MAR 19 1999

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Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,712,155 was filed on December 22, 1998, under 35 U.S.C. § 156. The patent does not now claim the approved product, its method of use or method of manufacturing, however, Reissue Application No. 09/144,502, filed August 31, 1998 contains claims to the method of manufacturing the active ingredient of ENBREL™. If the reissue application is allowed, the application as reissued may be subject to patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of ENBREL™.

The assistance of your Office is requested in confirming that the product identified in the application, ENBREL™, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Tyson
Senior Legal Advisor
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Office of the Deputy Assistant Commissioner
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